



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

OK BIOTECH CO., LTD.
JEN KE-MIN
1F, NO. 87, SEC. 2,
GONGDAOOWU ROAD
HSIN CHU CITY 30070 TAIWAN

August 14, 2014

Re: K132633

Trade/Device Name: OKmeter Direct Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: July 17, 2014
Received: July 15, 2014

Dear Dr. Jen, Ke-min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (*if known*)

K132633

Device Name

Okmeter Direct Blood Glucose Monitoring System

Indications for Use (Describe)

The OKmeter Direct Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper-arm, calf, thigh, or palm. The OKmeter Direct Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The OKmeter Direct Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The OKmeter Direct Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The OKmeter Direct Test Strips are for use with the OKmeter Direct Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upperarm, calf, thigh, or palm.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

5.1. General Information Establishment

- The assigned 510(k) number is : **K132633**
- Manufacturer: **OK Biotech Co., Ltd.**
- Address: 1F, No. 87, Sec. 2, Gongdaowu Road, Hsin Chu City, 30070, Taiwan, ROC
- Owner Number: **9090860**
- Contact Person: Dr. Jen, Ke-Min E-mail: ceirs.jen@msa.hinet.net
886-3-5208829 (Tel); 886-3-5209783 (Fax)
Address: No.58, Fu Chiun Street, Hsin Chu City, 30067, Taiwan, ROC
- Date Prepared: July 26, 2013

Device

- **Proprietary Name:** Okmeter Direct Blood Glucose Monitoring System
- **Common Name:** Blood Glucose Monitoring System
- **Classification Name:** SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER, Class II
- **Product Code:** NBW

5.2. Safety and Effectiveness Information

- **Predicate Device:**
Claim of Substantial Equivalence (SE) is made to *Okmeter Match Blood Glucose Monitoring System (K090609)*
- **Device Description:** Based on an electrochemical biosensor technology and the principle of capillary action, Okmeter Direct Blood Glucose Monitoring System only needs a small amount of blood. Capillary action at the end of the test strip draws the blood into the action chamber and your blood glucose result is precisely and displayed in 6 seconds.
- **Intended Use:**
The OKmeter Direct Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper-arm, calf, thigh, or palm. The OKmeter Direct Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The OKmeter Direct Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The OKmeter Direct Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The OKmeter Direct Test Strips are for use with the OKmeter Direct Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper-arm, calf, thigh, or palm.

● **Substantial Equivalence (SE)**

A claim of substantial equivalence is made to *Okmeter Match Blood Glucose Monitoring System (K090609)*. Both of them have the same working principle and technologies including sample volume, measuring time, detecting range, HCT range, calibration method, and memory data number. The major differences for the two devices are meter dimension, weight; especially the predicate device using two colors of the test strips and has some audible features but it is not for use by the visually impaired. Besides, the subject device and predicate device is same intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. Thus the differences are due to the feature design aspects, not relating to the safety or effectiveness aspects. They are substantially equivalent.

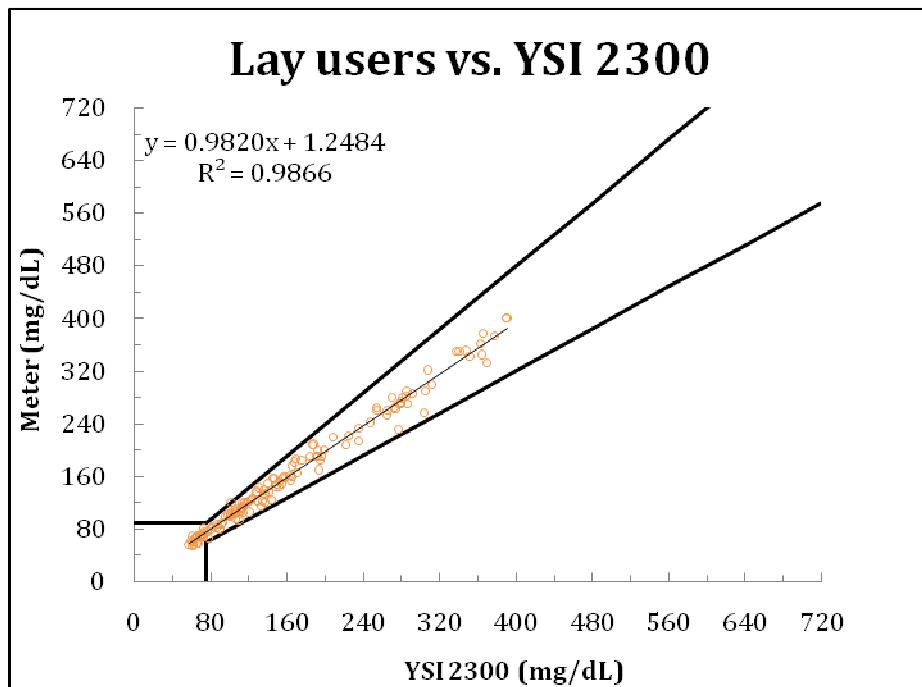
● **Synopsis of Test Methods and Results**

Pre-clinical and clinical data are employed upon submission of this 510(K) premarket notification according to the *Guidance Document for In Vitro Diagnostic Test System; Guidance for Industry and FDA* document provided by CDRH/ FDA.

For Home Users

The table below was based on a study done with 135 patients to see how well the OKmeter Direct Blood Glucose Monitoring System compared to the YSI 2300.

- Finger capillary whole blood



Results for glucose concentration<75 mg/dL(4.2 mmol/L)

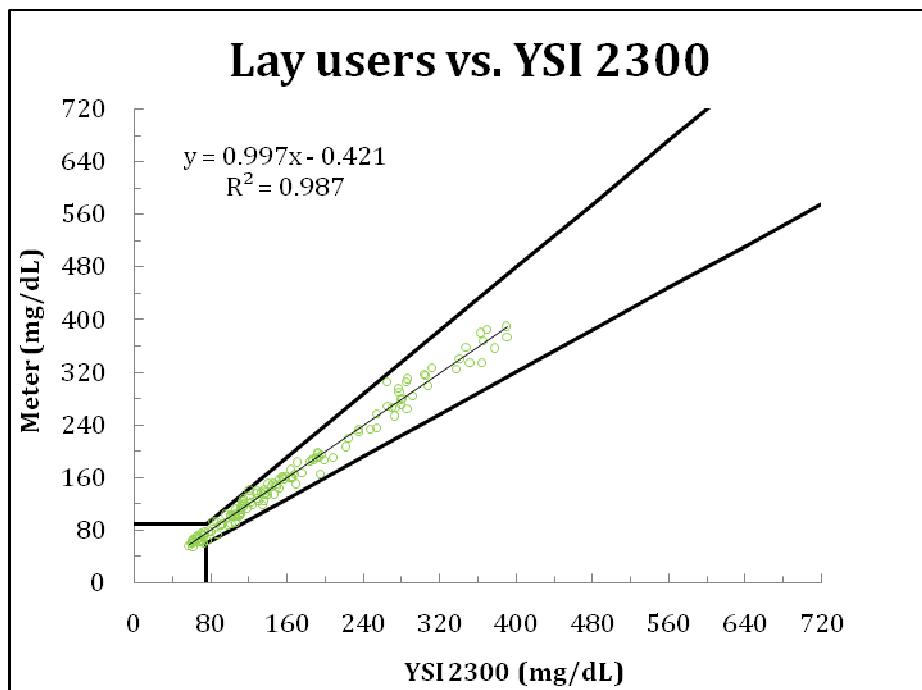
Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
15/21 (71%)	21/21 (100%)	21/21 (100%)

Results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
83/114 (73%)	100/114 (88%)	111/114 (97%)	114/114 (100%)

OKmeter Direct Blood Glucose Monitoring System vs. YSI 2300 Analyzer			
n	Slope	Intercept	R ²
135	0.982	1.2484	0.9866

- Palm capillary whole blood



Results for glucose concentration < 75 mg/dL (4.2 mmol/L)

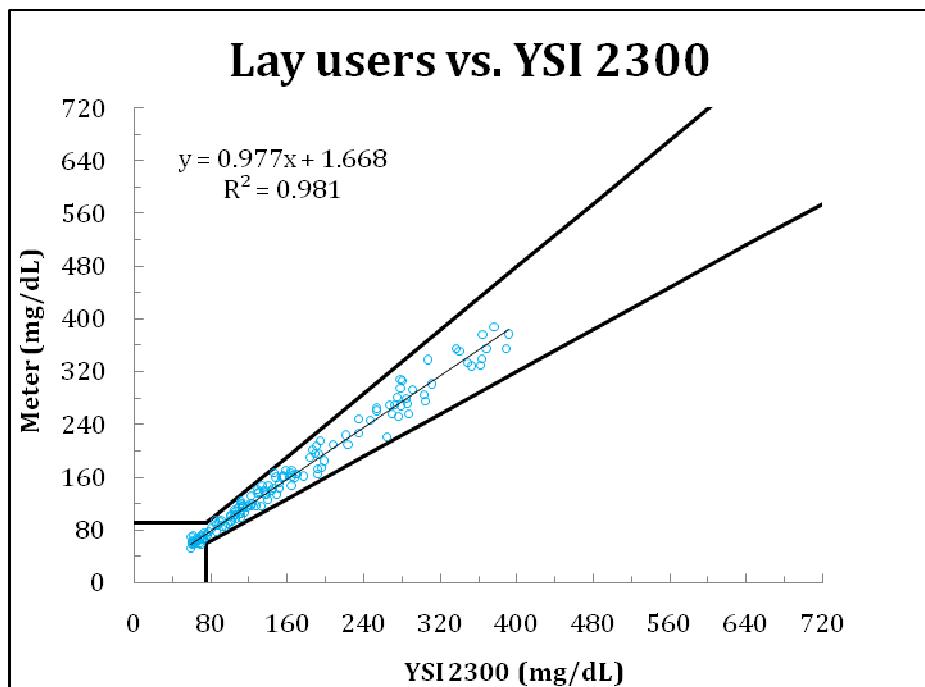
Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
15/21 (71%)	20/21 (95%)	21/21 (100%)

Results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
74/114 (65%)	102/114 (89%)	111/114 (97%)	114/114 (100%)

OKmeter Direct Blood Glucose Monitoring System vs. YSI 2300 Analyzer			
n	Slope	Intercept	R ²
135	0.9972	-0.4212	0.9874

- Forearm capillary whole blood



Results for glucose concentration<75 mg/dL(4.2 mmol/L)

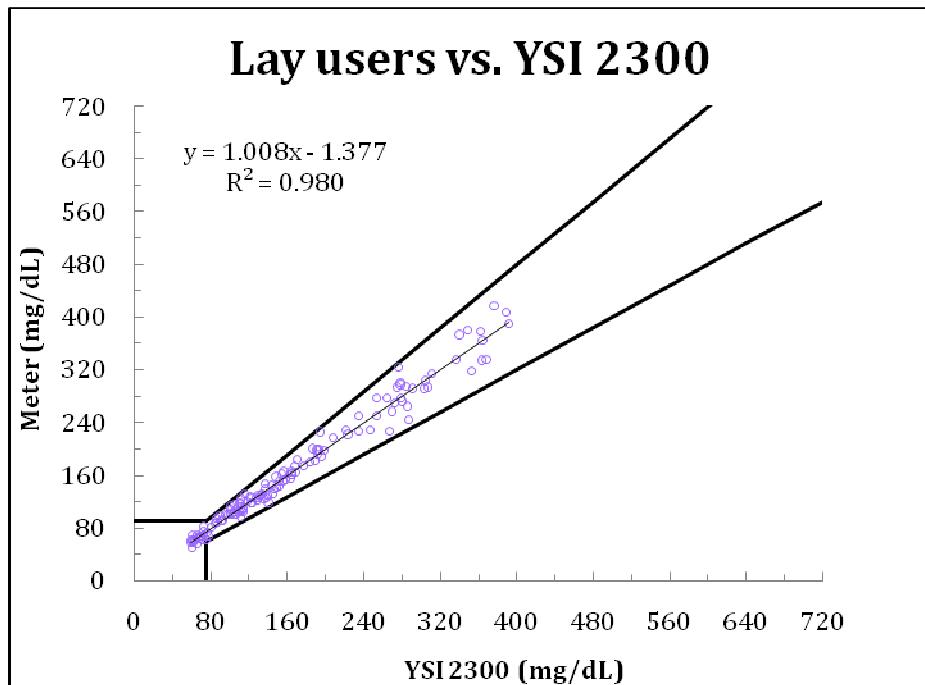
Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
15/21 (71%)	20/21 (95%)	21/21 (100%)

Results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
64/114 (56%)	99/114 (87%)	113/114 (99%)	114/114 (100%)

OKmeter Direct Blood Glucose Monitoring System vs. YSI 2300 Analyzer			
n	Slope	Intercept	R ²
135	0.9778	1.6689	0.9817

- Upper arm capillary whole blood



Results for glucose concentration<75 mg/dL(4.2 mmol/L)

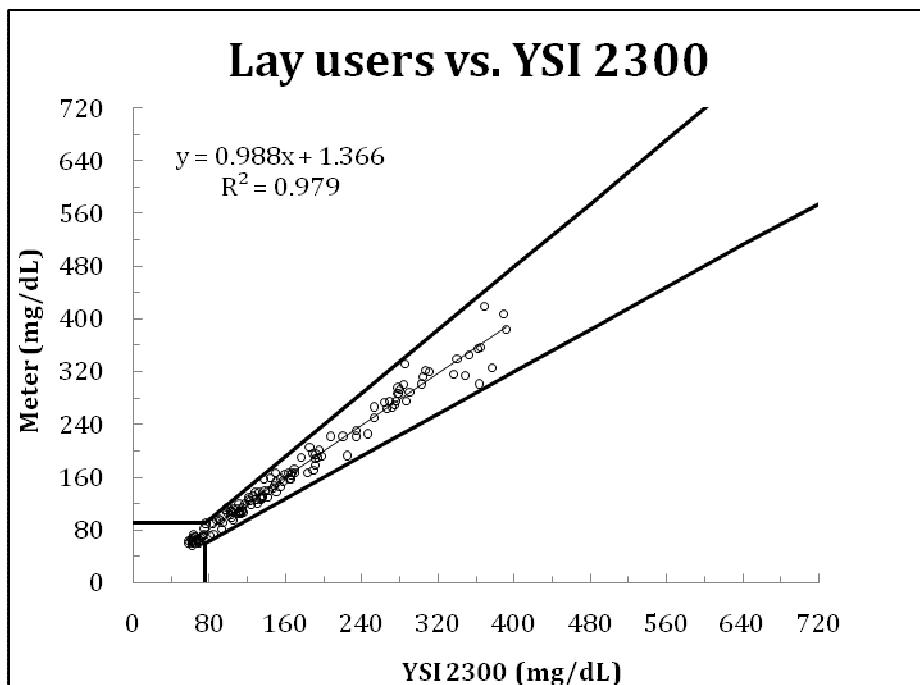
Within±5 mg/dL (Within±0.28 mmol/L)	Within±10 mg/dL (Within±0.56 mmol/L)	Within±15 mg/dL (Within±0.83 mmol/L)
14/21 (67%)	20/21 (95%)	21/21 (100%)

Results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

Within±5%	Within±10%	Within±15%	Within±20%
75/114 (66%)	102/114 (89%)	111/114 (97%)	114/114 (100%)

OKmeter Direct Blood Glucose Monitoring System vs. YSI 2300 Analyzer			
n	Slope	Intercept	R ²
135	1.0089	-1.377	0.9805

- Calf capillary whole blood



Results for glucose concentration < 75 mg/dL (4.2 mmol/L)

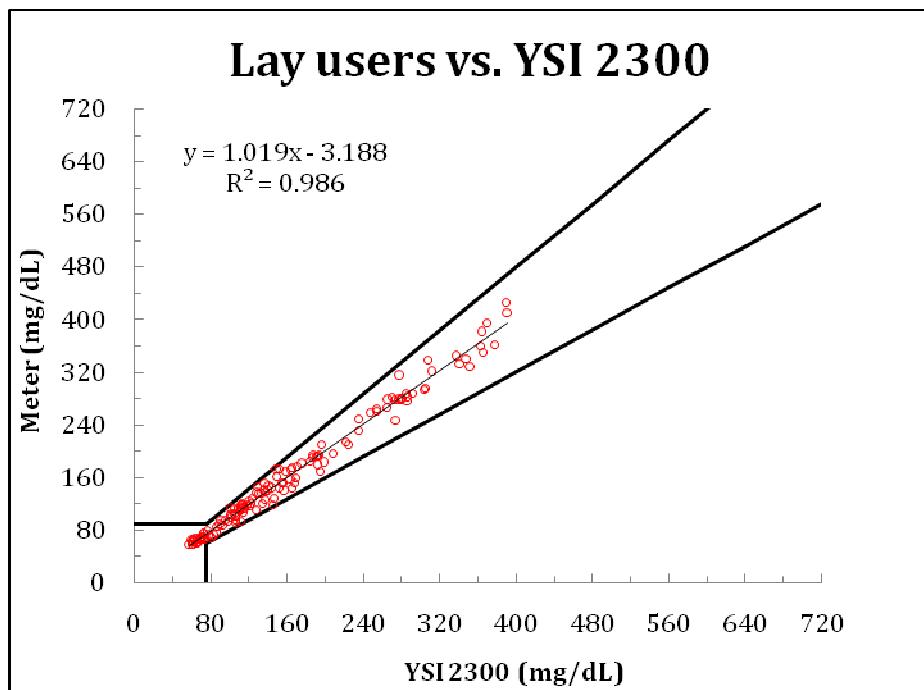
Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
14/21 (67%)	20/21 (95%)	21/21 (100%)

Results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
66/114 (58%)	98/114 (86%)	112/114 (98%)	114/114 (100%)

OKmeter Direct Blood Glucose Monitoring System vs. YSI 2300 Analyzer			
n	Slope	Intercept	R ²
135	0.9884	1.3662	0.9794

- Thigh capillary whole blood



Results for glucose concentration < 75 mg/dL (4.2 mmol/L)

Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
18/21 (86%)	21/21 (100%)	21/21 (100%)

Results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

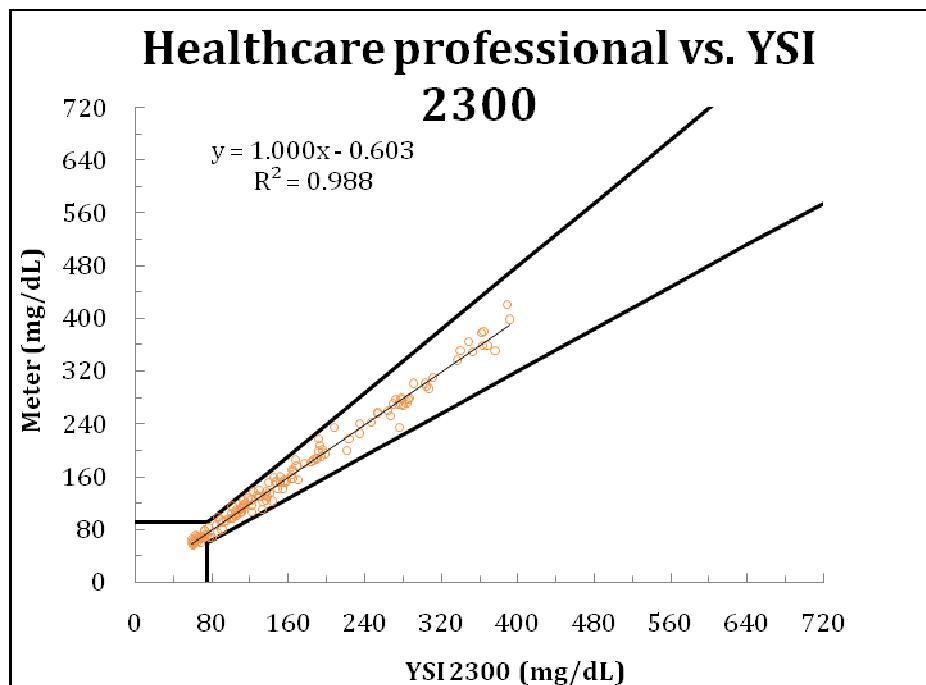
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
72/114 (63%)	96/114 (84%)	110/114 (96%)	114/114 (100%)

OKmeter Direct Blood Glucose Monitoring System vs. YSI 2300 Analyzer			
n	Slope	Intercept	R ²
135	1.0191	-3.1886	0.986

For Healthcare Professionals

The table below was based on a study done with 135 patients to see how well the OKmeter Direct Blood Glucose Monitoring System compared to the YSI 2300.

- Finger capillary whole blood



Results for glucose concentration<75 mg/dL(4.2 mmol/L)

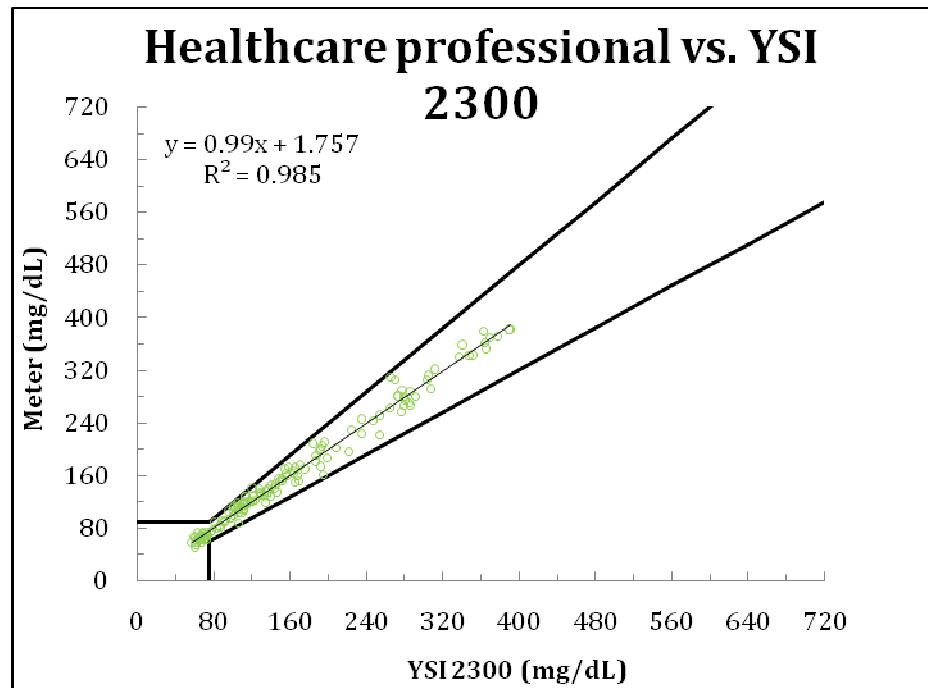
Within±5 mg/dL (Within±0.28 mmol/L)	Within±10 mg/dL (Within±0.56 mmol/L)	Within±15 mg/dL (Within±0.83 mmol/L)
17/21 (81%)	21/21 (100%)	21/21 (100%)

Results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

Within±5%	Within±10%	Within±15%	Within±20%
84/114 (74%)	100/114 (88%)	111/114 (97%)	114/114 (100%)

OKmeter Direct Blood Glucose Monitoring System vs. YSI 2300 Analyzer			
n	Slope	Intercept	R ²
135	1.0001	-0.6033	0.9884

- Palm capillary whole blood



Results for glucose concentration < 75 mg/dL (4.2 mmol/L)

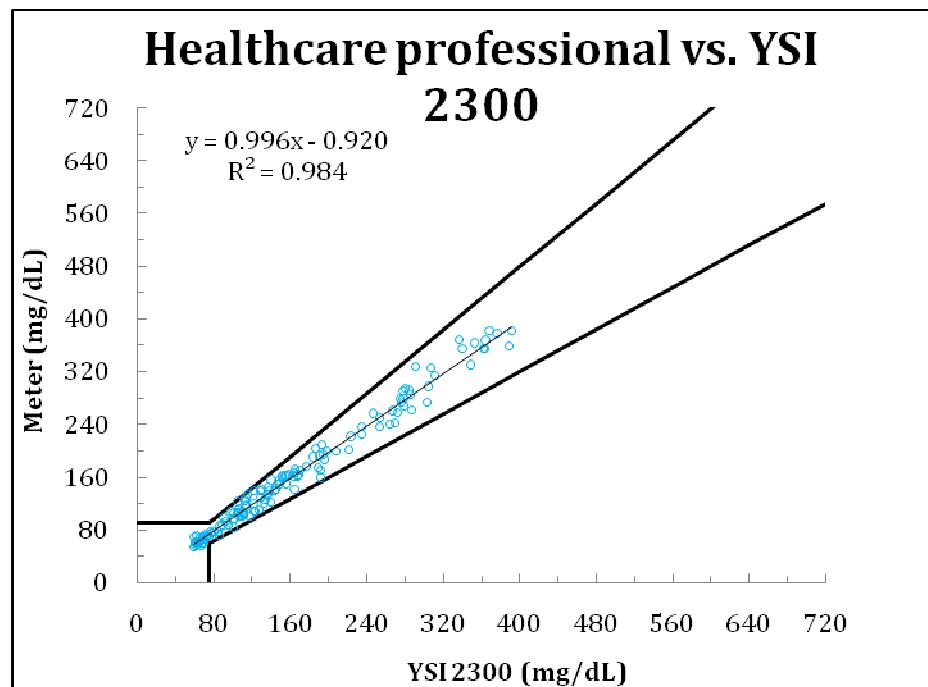
Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
14/21 (67%)	21/21 (100%)	21/21 (100%)

Results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
77/114 (68%)	99/114 (87%)	110/114 (96%)	114/114 (100%)

OKmeter Direct Blood Glucose Monitoring System vs. YSI 2300 Analyzer			
n	Slope	Intercept	R ²
135	0.99	1.7572	0.9859

- Forearm capillary whole blood



Results for glucose concentration < 75 mg/dL (4.2 mmol/L)

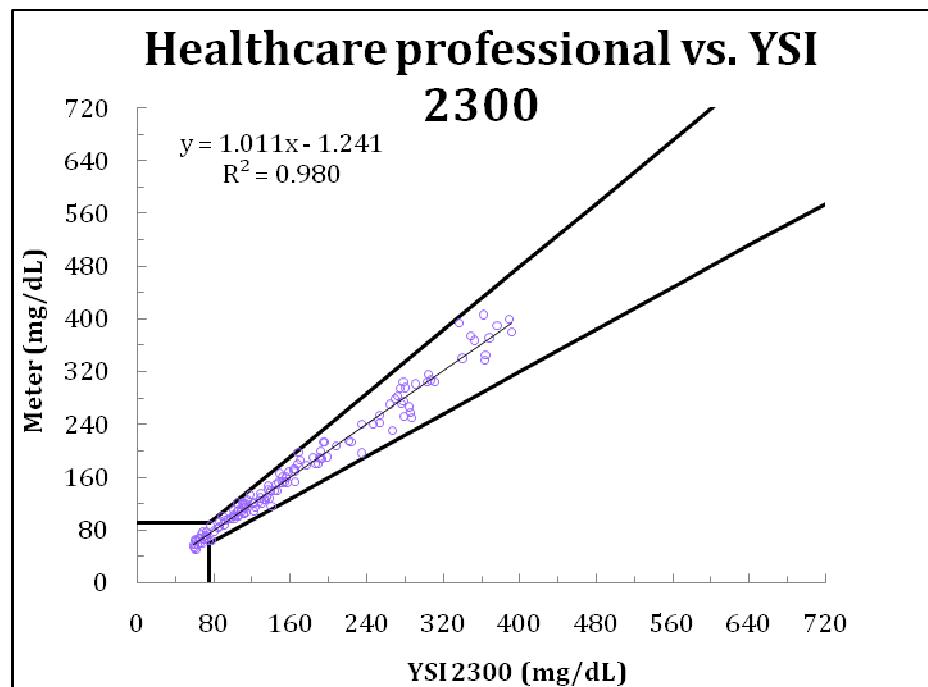
Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
14/21 (67%)	20/21 (95%)	21/21 (100%)

Results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
67/114 (59%)	97/114 (85%)	109/114 (96%)	114/114 (100%)

OKmeter Direct Blood Glucose Monitoring System vs. YSI 2300 Analyzer			
n	Slope	Intercept	R ²
135	0.9962	-0.9202	0.9843

- Upper arm capillary whole blood



Results for glucose concentration < 75 mg/dL (4.2 mmol/L)

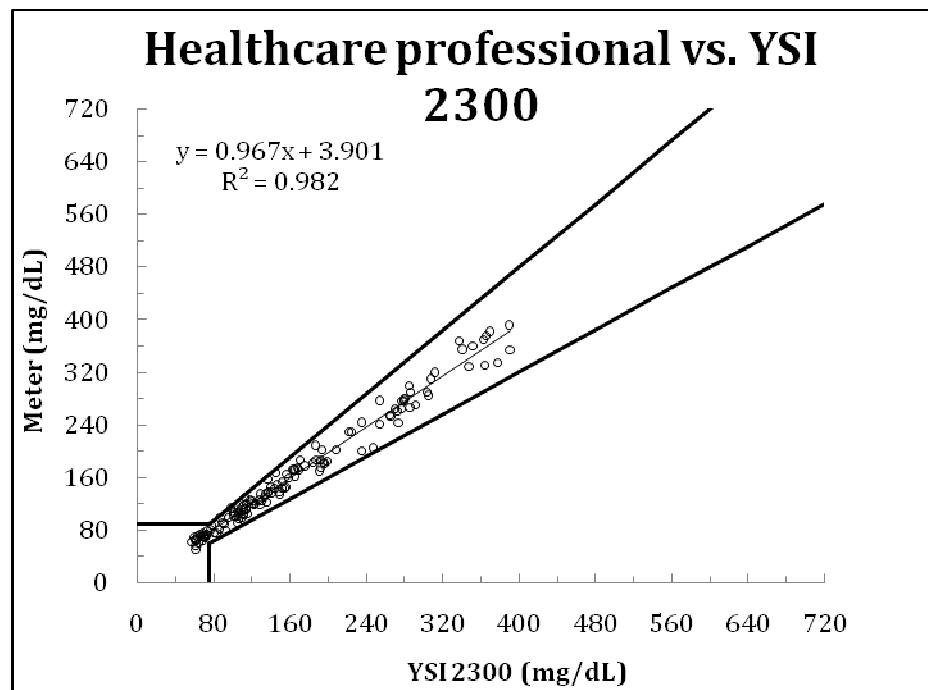
Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
15/21 (71%)	20/21 (95%)	21/21 (100%)

Results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
69/114 (61%)	100/114 (88%)	109/114 (96%)	114/114 (100%)

OKmeter Direct Blood Glucose Monitoring System vs. YSI 2300 Analyzer			
n	Slope	Intercept	R^2
135	1.0111	-1.2414	0.9808

- Calf capillary whole blood



Results for glucose concentration < 75 mg/dL (4.2 mmol/L)

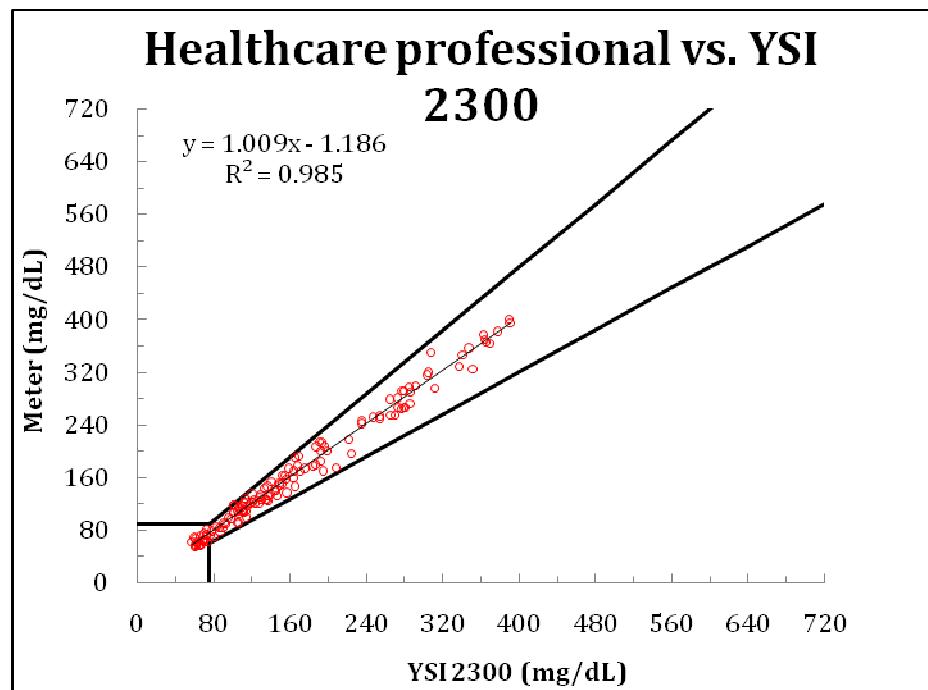
Within \pm 5 mg/dL (Within \pm 0.28 mmol/L)	Within \pm 10 mg/dL (Within \pm 0.56 mmol/L)	Within \pm 15 mg/dL (Within \pm 0.83 mmol/L)
16/21 (76%)	20/21 (95%)	21/21 (100%)

Results for glucose concentration \geq 75 mg/dL (4.2 mmol/L)

Within \pm 5%	Within \pm 10%	Within \pm 15%	Within \pm 20%
67/114 (59%)	99/114 (87%)	109/114 (96%)	114/114 (100%)

OKmeter Direct Blood Glucose Monitoring System vs. YSI 2300 Analyzer			
n	Slope	Intercept	R ²
135	0.967	3.9017	0.9823

- Thigh capillary whole blood



Results for glucose concentration < 75 mg/dL (4.2 mmol/L)

Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
14/21 (67%)	20/21 (95%)	21/21 (100%)

Results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
74/114 (65%)	97/114 (85%)	109/114 (96%)	114/114 (100%)

OKmeter Direct Blood Glucose Monitoring System vs. YSI 2300 Analyzer			
n	Slope	Intercept	R ²
135	1.0095	-1.1861	0.9856

Comparison Table

Similarities:

Item	Okmeter Match Blood Glucose Monitoring System (K090609)	Okmeter Direct Blood Glucose Monitoring System (K132633)
Intend Use	<p>The Okmeter Match Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative site testing in this system can be used only during steady-state blood glucose conditions. The meter has some audible features but it is not for use by the visually impaired.</p>	<p>The OKmeter Direct Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper-arm, calf, thigh, or palm. The OKmeter Direct Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.</p> <p>The OKmeter Direct Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The OKmeter Direct Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).</p> <p>The OKmeter Direct Test Strips are for use with the OKmeter Direct Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper-arm, calf, thigh, or palm.</p>
Test Principle	Electrochemical biosensor with carbon electrodes	same
Specimen Type	capillary whole blood, alternative sites	same
Sample Volume	0.7 μ L	same
Measuring Time	6 sec	same
Calibration Method	Control Solution	same

Operating Temperature	10 to 40 °C	same
Strip Storage Temperature	4 to 40 °C	same

Differences:

Item	Okmeter Match Blood Glucose Monitoring System (K090609)	Okmeter Direct Blood Glucose Monitoring System (K132633)
Test Strip	OKmeter voice blood glucose test strip A and strip B (identical structure design for different color, white for strip A and Green for strip B)	OKmeter Direct blood glucose test stripB
Meter Dimension	105(L) x 55(W) x 18(H)	unit: mm 95(L) x 45(W) x 18.4(H)
Meter Weight	82 g	with battery: 70g
Detecting Range	25 ~ 580 mg/dL	20 ~ 600 mg/dL
HCT Range	20 ~ 55 %	20 ~ 60 %
Speaking Function	Yes (some audible features but it is not for use by the visually impaired)	No
Memory Storage	450 test results	180 test results